UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Little Gem Life Sciences LLC, individually and on behalf of a class of persons similarly situated,

Plaintiff,

v.

Orphan Medical, Inc., John H. Bullion, and Timothy G. McGrath,

Defendants.

MEMORANDUM OPINION AND ORDER
Civil No. 06-1377 ADM/AJB

Joel C. Feffer, Esq., Harwood Feffer LLP, New York, NY, and Gregg M. Fishbein, Esq., Lockridge Grindal Nauen P.L.L.P., Minneapolis, MN, on behalf of Plaintiff.

Peter W. Carter, Esq., Dorsey & Whitney LLP, Minneapolis, MN, on behalf of John H. Bullion and Timothy G. McGrath, and Richard G. Wilson, Esq., Maslon Edelman Borman & Brand LLP, Minneapolis, MN, on behalf of Orphan Medical, Inc.

I. INTRODUCTION

On June 8, 2006, the undersigned United States District Judge heard oral argument on Defendants Orphan Medical, Inc. ("Orphan Medical"), John H. Bullion ("Bullion"), and Timothy G. McGrath's ("McGrath") (collectively "Defendants") Motion to Dismiss [Docket No. 35] Plaintiff Little Gem Life Sciences LLC's Amended Complaint ("Little Gem") [Docket No. 33]. In its Amended Complaint, Little Gem alleges that Defendants violated federal securities laws by negligently making a false statement and omitting certain information from a proxy statement issued in connection with a merger transaction. For the reasons set forth herein, Defendants' Motion to Dismiss is granted.

II. BACKGROUND[1]

On February 16, 2007, this Court issued an Order [Docket No. 32] dismissing without prejudice Little Gem's initial Complaint [Docket No. 1] for failure to plead an omission with the particularity required by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 109 Stat. 737. The facts alleged in Little Gem's Amended Complaint largely repeat the allegations of the initial Complaint, which were discussed in the February 2007 Order. Therefore, only a brief summary of the previously discussed facts is necessary here.

Orphan Medical is a specialty pharmaceutical company whose focus is on sleep disorders, pain, and other central nervous system disorders. Am. Compl. ¶ 9. Bullion was Orphan Medical's Chief Executive Officer and served on its Board of Directors. Id. ¶ 10. McGrath was Orphan Medical's Chief Financial Officer, Principal Accounting Officer, and a Vice President. Id. ¶ 11.

Orphan Medical's lead product is Xyrem, an oral solution for the treatment of cataplexy associated with narcolepsy. Id. ¶ 25; Leventhal Decl. [Docket No. 19] Ex. B at 2.[2] In June 2004, Orphan Medical initiated a clinical trial to assess Xyrem for the treatment of fibromyalgia. Leventhal Decl. Ex. B at 2. Orphan Medical's March 16, 2005, Form 10-K states that Orphan

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[1] In considering a motion to dismiss, the pleadings are construed in the light most favorable to the nonmoving party, and the facts alleged in the complaint must be taken as true. Hamm v. Groose, 15 F.3d 110, 112 (8th Cir. 1994).

[2] The following documents provided by Defendants in the Leventhal Declaration are considered as central to the Amended Complaint: Exhibits A (Orphan Medical's May 20, 2005, Proxy Statement) and E (a transcript of an April 26, 2005, conference call). See Stahl v. Dep't of Agric., 327 F.3d 697, 700-01 (8th Cir. 2003) (discussing documents a court may consider on a motion to dismiss). Exhibit B (the March 16, 2005, 10-K) is not central to the Amended Complaint, but provides useful dates and details. The Court refers to Exhibit B only to establish context regarding the Xyrem clinical trial.

Medical expected to announce the results of the fibromyalgia trial in the second half of 2005. Id.

On April 18, 2005, Orphan Medical's board of directors approved a merger agreement whereby almost all of Orphan Medical's publicly owned stock would be purchased and Orphan Medical would become a subsidiary of Jazz Pharmaceuticals, Inc. ("Jazz"). Leventhal Decl. Ex. A at 16. On May 20, 2005, Orphan Medical filed a Proxy Statement announcing a June 22, 2005, shareholder meeting to vote on the proposed merger. Id. Ex. A. Under the merger agreement, each Orphan Medical stockholder would receive $10.75 per share of common stock. Id.

The Proxy Statement refers to an opinion prepared by Banc of America Securities LLC ("Banc of America"), the financial advisor to Orphan Medical's board of directors, that the proposed merger was financially fair to holders of Orphan Medical's common stock. Id. at 3-4, 16-24. Banc of America's two-page fairness opinion, reproduced in full as Appendix C to the Proxy Statement, states that Banc of America reviewed financial forecasts prepared by Orphan Medical's management as of April 18, 2005. Id. at C-2.

The merger was approved by a majority of Orphan Medical's shareholders at the June 22, 2005, shareholder meeting. Little Gem, an Orphan Medical shareholder at the time of the merger, filed its initial Complaint on April 10, 2006, on behalf of itself and a class of holders of Orphan Medical common stock as of May 23, 2005. The initial Complaint asserted claims against Defendants under sections 14(a) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), alleging that "[t]he Proxy Statement's repeated references to the Financial Advisor's opinion are materially false and misleading because the Proxy Statement omits to disclose that the financial advisor failed to consider the full impact of likely significant

expansions of the prospective patient base for Xyrem." Compl. ¶ 26. This Court's February 2007 Order found that the initial Complaint failed to satisfy the PSLRA's heightened pleading requirements. Little Gem's Amended Complaint attempts to remedy the deficiencies of the original Complaint.

III. DISCUSSION

A. Motion to Dismiss and Pleading Standards

Rule 12 of the Federal Rules of Civil Procedure provides that a party may move to dismiss a complaint for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). In considering a motion to dismiss, the pleadings are construed in the light most favorable to the nonmoving party, and the facts alleged in the complaint must be taken as true. Hamm v. Groose, 15 F.3d at 112; Ossman v. Diana Corp., 825 F. Supp. 870, 879-80 (D. Minn. 1993). Any ambiguities concerning the sufficiency of the claims must be resolved in favor of the nonmoving party. Ossman, 825 F. Supp. at 880. "A motion to dismiss should be granted as a practical matter . . . only in the unusual case in which the plaintiff includes allegations that show on the face of the complaint that there is some insuperable bar to relief." Frey v. City of Herculaneum, 44 F.3d 667, 671 (8th Cir. 1995).

Under Rule 8(a) of the Federal Rules of Civil Procedure, pleadings "shall contain a short and plain statement of the claim showing that the pleader is entitled to relief." A pleading must contain "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1974 (2007).

B. Defendants' Motion to Dismiss[3]

1. Claims under Section 14(a) of the Exchange Act

Section 14(a) of the Exchange Act aims "to prevent management or others from obtaining authorization for corporate action by means of deceptive or inadequate disclosure in proxy solicitation." J. I. Case Co. v. Borak, 377 U.S. 426, 431 (1964). Section 14(a) prohibits proxy solicitations that violate rules promulgated by the SEC. 15 U.S.C. § 78n(a). SEC Rule 14a-9 prohibits a proxy solicitation by means of a proxy statement that "contain[s] any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading." 17 C.F.R. § 240.14a-9. Plaintiffs establish a violation of § 14(a) and Rule 14a-9 by showing: (1) the proxy statement contains a material omission; (2) the defendants negligently drafted the proxy statement; and (3) the proxy caused an injury to plaintiffs. In re BankAmerica Corp. Sec. Litig., 78 F. Supp. 2d 976, 988-89 (E.D. Mo. 1999).

Defendants argue that Little Gem's Amended Complaint must be dismissed because it fails to plead a false statement or an omission with the particularity required by the PSLRA. In response, Little Gem contends that the heightened pleading requirements of the PSLRA do not

[3] Little Gem argues that Defendants improperly rely on matters outside the Amended Complaint and therefore Defendants' Motion to Dismiss should be considered a motion for summary judgment. See Fed. R. Civ. P. 12(b) ("If . . . matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment . . . and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56."). Defendants have made factual assertions that go beyond the allegations of the Amended Complaint. However, the Court has not considered those assertions in deciding the instant Motion to Dismiss.

apply to claims under § 14(a) of the Exchange Act. In the alternative, Little Gem argues that it has pled a false statement and an omission with the requisite particularity.

a. Whether the PSLRA's Heightened Pleading Requirements Apply to Claims Under Section 14(a) of the Exchange Act

The February 2007 Order held that Little Gem's initial Complaint failed to plead an omission with the particularity required by the PSLRA. In support of its argument that the Amended Complaint survives Defendants' Motion to Dismiss, Little Gem seeks to revisit the issue of whether the PSLRA applies to claims under § 14(a) of the Exchange Act. However, under the law of the case doctrine, "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." First Union Nat'l Bank v. Pictet Overseas Trust Corp., 477 F.3d 616, 620 (8th Cir. 2007) (quotation marks and citation omitted). Although it is unnecessary to revisit the issue, Little Gem's arguments will be briefly addressed.

> The PSLRA's heightened pleading provision, 15 U.S.C. § 78u-4(b)(1), specifies that:
>
> In any private action arising under this chapter in which the plaintiff alleges that the defendant—
>
> (A) made an untrue statement of a material fact; or
>
> (B) omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances in which they were made, not misleading;
>
> the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

Little Gem's claim is premised on a violation of § 14(a) of the Exchange Act, which is codified at 15 U.S.C. § 78n(a). The PSLRA's heightened pleading provision and § 14(a) of the Exchange Act are both codified in Chapter 2B of Title 15 of the United States Code, and Little Gem has alleged that Defendants made false statements of material fact and omitted material information

that made the inclusion of Banc of America's fairness opinion misleading. Therefore, the PSLRA's heightened pleading provision applies to Little Gem's allegations.

Arguing against this result, Little Gem refers to the heading of 15 U.S.C. § 78u-4(b), which is "Requirements for securities fraud actions." Little Gem argues that its § 14(a) claim is based on negligence as opposed to fraud, and therefore only the "short and plain statement" pleading requirement of Federal Rule of Civil Procedure 8 applies. However, it is a well-settled rule of statutory construction that "the title of a statute and the heading of a section cannot limit the plain meaning of the text." Bhd. of R.R. Trainmen v. Baltimore & Ohio R.R., 331 U.S. 519, 528-29 (1947). "Section and subchapter titles . . . can only assist in clarifying ambiguity." Owner-Operated Indep. Drivers Ass'n v. New Prime, Inc., 192 F.3d 778, 784 (8th Cir. 1999) (quotation marks and citation omitted). There is no ambiguity in 15 U.S.C. § 78u-4(b); therefore heightened pleading requirements apply in this case.[4]

b. Whether Little Gem's Allegations Satisfy the PSLRA

Little Gem's Amended Complaint alleges that the May 20, 2005, Proxy Statement's claim that "Orphan Medical is currently conducting a proof-of-principle clinical trial to assess Xyrem as a treatment for the symptoms of fibromyalgia syndrome" is materially false and

[4] Most courts to address the issue have reached the same conclusion. See Knollenberg v. Harmonic, Inc., 152 Fed. Appx. 674, 682-83 (9th Cir. Nov. 8, 2005) (stating that "the PSLRA pleading requirements apply to claims brought under Section 14(a) and Rule 14a-9"); In re U.S. West, Inc. Sec. Litig., 65 Fed Appx. 856, 860 (3d Cir. May 30, 2003); Fisher v. Kanas, 467 F. Supp. 2d 275, 281 (E.D.N.Y. 2006); Bond Opportunity Fund v. Unilab Corp., 2003 WL 21058251, *3 (S.D.N.Y. May 9, 2003). But see Blau v. Harrison, 2006 WL 850959, *6 (N.D. Ill. March 24, 2006) (concluding that § 14(a) claims based on negligence are not subject to PSLRA's heightened pleading requirements). Little Gem's reliance on Kennedy v. Venrock Associates, 348 F.3d 584 (7th Cir. 2003) for the proposition that the PSLRA's heightened pleading requirements do not apply to § 14(a) claims is misplaced because Kennedy does not address the PSLRA.

misleading because:

> By mid-January 2005, patient enrollment in the trial was completed. The trial itself was to last three months, consisting of a one-month "washout period," during which enrolled patients were to be drug-free, followed by an eight-week treatment period. Accordingly, the fibromyalgia clinical trial was completed, and the data available, on or about April 15, 2005, more than a month before Orphan Medical disseminated the Proxy Statement.
>
> Moreover, because the clinical trial's enrollment was less than 200 patients, lengthy analysis of the data was not required and the positive results of the trial were available to defendants, if not at the time the Proxy Statement was first disseminated on May 25, 2005, at least by the time of Orphan Medical's stockholders' meeting on June 22, 2005.

Am. Compl. ¶¶ 27-28.

However, these allegations, which are based on information and belief, suffer from the same deficiencies as the allegations in the initial Complaint. Little Gem has failed to adequately allege (1) when the results from the trial were prepared, (2) who prepared the results, (3) whether the results were in preliminary or final form, (4) when the results were reviewed by Orphan Medical's officers; and (5) which Orphan Medical officers reviewed the results. See Cal. Pub. Employees' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 154 (3d Cir. 2004) (finding conclusory assertion that defendants had access to undisclosed information before merger vote was "patently insufficient").

To support its assertion that the positive Xyrem results were available by June 22, 2005, Little Gem relies on allegations that:

> Depomed, Inc., also a NASDAQ-listed company, conducted a similarly sized clinical trial to evaluate one of its drugs. Enrollment was completed October 5, 2006, the last person in the four-week study was treated on November 5, 2006, and the data was analyzed and distributed in approximately one month and publicly released on December 12, 2006.

Am. Compl. ¶ 29. However, these meager allegations fail to show that the Depomed clinical trial is relevant in determining how long Orphan Medical needed to analyze the Xyrem data.

The only obvious similarity between the two trials is that both involved approximately two-hundred patients. However, the Depomed clinical trial lasted one month, whereas Orphan Medical's Xyrem clinical trial lasted three months. Further, there is no allegation that the Depomed study and the Xyrem study were performed under similar conditions and required analysis of similar volumes of data. Little Gem's vague allegations using the Depomed analogy provide no basis for a conclusion that the formal results of the Xyrem clinical trial for fibromyalgia were available by April 15, 2005, May 20, 2005 (the date of the Proxy Statement), or June 22, 2005 (the date of merger vote).

In the alternative, Little Gem alleges that "[e]ven if the analysis of the fibromyalgia clinical trial data was not formally available by June 22, 2005, Orphan Medical's management could easily have known the results because Xyrem has a well-known dose dependent side effect profile. Thus even without unblinding, professionals could reasonably be expected to determine who was taking Xyrem and who was taking the placebo . . . ." Id. ¶ 30. However, these speculative allegations fail to describe any circumstances under which Orphan Medical's management allegedly viewed raw trial data before the formal data analysis was complete. Further, Little Gem's assertion that "professionals could reasonably be expected to determine who was taking Xyrem" would effectively amount to unblinding the study before it was completed. Little Gem has provided no factual basis to support its conjecture that "professionals" would disregard protocol by unblinding the study and prematurely disclosing the unblinded information to Orphan Medical's senior management. See 21 C.F.R. § 314.126(b)(5) ("An adequate and well-controlled study has the following characteristics: . . . Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the

data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.").

Little Gem also suggests that because Bullion and McGrath "were required to provide Jazz with a certificate of compliance at the closing of the merger . . . it was incumbent upon both of them to keep apprised of the developments in the fibromyalgia trial." Am. Compl. ¶ 30; see Leventhal Decl. Ex. A at A-35. However, Little Gem has not explained how Bullion and McGrath's obligation to certify that Orphan Medical had performed its contractual obligations to Jazz, and that Orphan Medical's representations and warranties to Jazz were still true, amounted to a duty to violate the clinical trial protocol and view the blinded trial results before the merger closed.

Little Gem also argues that the merger agreement's "Material Adverse Effect" clause provides support for the conclusion that Defendants knew the positive results of the Xyrem clinical trial at the time of the merger. Am. Compl. ¶ 31. To reach this conclusion, Little Gem first argues that under the merger agreement, "Jazz, as a practical matter, had the ability to delay the consummation of the merger until November 30, 2005." Id. Second, Little Gem relies on language in the merger agreement imposing a condition precedent on the merger that "[n]o Material Adverse Effect shall have occurred and be continuing." Leventhal Decl. Ex. A at A-35. Third, Little Gem construes the merger agreement's definition of Material Adverse Effect as including negative "data relating solely to the efficacy of Xyrem in the treatment of fibromyalgia in [Orphan Medical's] pending . . . proof of principle clinical trial." Am. Compl. ¶ 31. Therefore, Little Gem concludes that "[t]he merger agreement, in effect, gave Jazz an option to acquire Orphan Medical, contingent on the results of the fibromyalgia proof-of-principle clinical

trial," and Jazz would not have closed the merger on June 24, 2005, unless Defendants had disclosed positive results regarding Xyrem. Id.

However, Little Gem's argument finds no support in the language of the merger agreement. The merger agreement's definition of "Material Adverse Effect" provides in relevant part:

> Notwithstanding any of the foregoing, (1) any change, event or occurrence (except with respect to any data relating solely to the efficacy of Xyrem in the treatment of fibromyalgia in the Company's pending SXB-26 proof of principle clinical trial) which, individually or in the aggregate, would reasonably be expected to have a material adverse effect on the results or prospects of Xyrem . . . shall . . . be deemed to be a Material Adverse Effect.

Leventhal Decl. Ex. A at A-7. Under the plain language of this clause, data from the Xyrem fibromyalgia proof of principle clinical trial was expressly carved out from the definition of a Material Adverse Effect. Therefore, Little Gem's argument that the Material Adverse Effect Clause supports an inference that Defendants accessed and disclosed data from the fibromyalgia trial to Jazz prior to the merger closing date is rejected.

Next, Little Gem alleges that "just two days before Orphan Medical's stockholders voted on the proposed merger, i.e. June 20, 2005, Jazz raised $100,000,000 in additional capital in order to finance the development of Xyrem as a treatment for fibromyalgia." Am. Compl. ¶ 31. Based on this allegation, Little Gem argues that a finder of fact could infer that Defendants provided Jazz with the results of the clinical trial by June 22, 2005. However, Little Gem's Amended Complaint provides no basis for the speculative conclusion that Jazz raised the $100 million to finance the development of Xyrem as a treatment for fibromyalgia. Little Gem has failed to plead with particularity facts that support its belief that Defendants were aware of positive Xyrem trial data before the merger vote on June 22, 2005.

Little Gem has also alleged that the Proxy Statement's references to Banc of America's fairness opinion "are materially false and misleading because the Proxy Statement omits to disclose that [Banc of America] failed to consider the positive results from the fibromyalgia clinical trial." Id. ¶ 34. However, this allegation cannot survive Defendants' Motion to Dismiss because Little Gem has not adequately pled with particularity that Defendants were aware of positive results before the merger vote.

Finally, Little Gem alleges that during a conference call in April 2005, Bullion promised that the fibromyalgia data would be released in the Proxy Statement. Id. ¶ 35; see Leventhal Decl. Ex. E. However, the Court has previously determined that Bullion's statements during the conference call cannot be read as a promise that specific data regarding the fibromyalgia clinical trial would be disclosed in the Proxy Statement. See February 16, 2007, Order at 9. Little Gem's Amended Complaint fails to plead the facts underlying a material false statement or a material omission with the particularity required by the PSLRA. Therefore, Little Gem's § 14(a) claims must be dismissed and it is unnecessary to address the remaining grounds for dismissal raised by Defendants.

2. Claims under Section 20(a) of the Exchange Act

The Amended Complaint asserts that Bullion and McGrath are individually liable as controlling persons within the meaning of § 20(a) of the Exchange Act.[5] Little Gem recognizes that liability under § 20(a) is premised upon liability under § 14(a). Since Defendants' Motion to

[5] "Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a).

Dismiss is granted regarding the § 14(a) claims, the § 20(a) claims must also be dismissed.

3. Dismissal With Prejudice

Little Gem has now twice failed to plead a false statement or an omission with the particularity required by the PSLRA. Under these circumstances, the Court finds that further amendment would be futile. Therefore, Little Gem's Amended Complaint is dismissed with prejudice. See Knapp v. Hanson, 183 F.3d 786, 790 (8th Cir. 1999) (noting that "futility constitutes a valid reason for denial of a motion to amend").

IV. CONCLUSION

Based upon the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion to Dismiss [Docket No. 35] is **GRANTED**: and
2. Plaintiff's Amended Complaint [Docket No. 33] is **DISMISSED WITH PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: September 13, 2007.